REMARKS

Claims 1, 3 to 36, 38 to 48 and 50 to 75 are pending. The Examiner withdrew claims 7 to 11, 30 to 32, 34, 39 to 41, 44, 54 to 58, 66 to 68, 70, and 73 to 75 as being drawn to a non-elected species.

The Examiner rejected claims 1, 3 to 6, 12 to 29, 33, 35, 37, 38, 42, 43, 45 to 48, 50 to 53, 59 to 65, 69, 71 and 72 under 35 U.S.C. § 103(a) as being unpatentable over Shanley et al. (U.S. Patent No. 6,290,673) in view of Fogarty (U.S. Patent No. 4,774,949). Applicant respectfully traverses this rejection of the claims.

Claims 1, 36, 42, 43, 45, and 72 are the only pending independent claims under examination. Each of these claims include a catheter having first, second and third elongate tubular bodies and an elongate member joining the first and second elongate bodies. Each of these claims further recites that "the proximal portion of the third elongate tubular body is maintained within the lumen of the first elongate tubular body by one or more magnetic or mechanical stops." In paragraph 3 of the Office Action the Examiner states that "Shanley teaches a catheter with a first elongate tubular body (72), a second elongate tubular body (14), an elongate member (76), and a third elongate tubular body (52)." The Examiner further states that the "expandable sheath (30) acts as a mechanical stop which can pin the guide wire to hold it in place, especially with [when] the guide wire is being used to deliver a balloon." The Examiner refers to Col. 6 at line 40 and Col. 7 at lines 20 to 65 of Shanley to support these conclusions. Applicant respectfully submits that the Examiner has misconstrued the structure and function of the device disclosed in Shanley.

Shanley discloses a delivery system for implanting an expandable tissue supporting device at a lumen junction or bifurcation. A detailed view of the tissue supporting device 30 (referred to by the Examiner as an "expandable sheath") is

shown in FIG. 2a. The tissue supporting device 30 is shown in more simplified form in the remainder of the drawings. The system includes a balloon catheter. The system also includes a guide member used to assist in placing the tissue supporting device at the junction of the body lumen. In the embodiment shown in FIGS. 9 and 10 the guide member 70 includes a main loop 14 and an auxiliary loop 72. (Col. 7, lines 1 to 6). The main loop 14 projects through a side port 32 of the tissue supporting device. The system also includes two guidewires used to deliver the tissue supporting device. Specifically, the system includes a main artery guidewire 50 and a branch artery guidewire 52. Prior to insertion of the catheter the two guidewires are installed by the operator. The main artery guidewire is inserted into the main artery and the branch artery guidewire is inserted into the branch artery. The catheter is then tracked over the main guidewire. (Col. 6, lines to 15). The branch artery guidewire is inserted into loops 14 and 72 (FIG. 10). The assembly is then advanced to the site of the bifurcation. As the catheter assembly approaches the bifurcation the clevis formed by the tissue supporting device 30 and the branch artery guidewire 52 comes to rest against the distal side of the branch artery opening. (Col. 6, lines 14 to 18).

It is clear that the system described in Shanley has no structure which functions as a stop to maintain a proximal portion or any other portion of the branch guidewire in the loop 14. In use the loop 14 is free to track over the branch artery guidewire without limitation. However, the Examiner states that the tissue supporting device (expandable sheath) 30 acts as a mechanical stop which can pin the guidewire to hold it in place. Specifically, the Examiner states that "Shanley teaches that expanding the balloon sheath 30 causes the guide wire to be pinned against the vessel wall, which secures the orientation of the guide wire along the branch vessel for delivery of a balloon to the branch vessel." (Office Action,

paragraph 4). Applicant respectfully submits that the device disclosed in Shanley does not function in the manner described by the Examiner.

After the delivery assembly has been advanced to the bifurcation Shanley describes the manner in which the tissue supporting device is deployed. First, pressure is increased in the catheter balloon until the distal end of the tissue supporting device expands to the lumen diameter of the main artery. This locks the tissue supporting device in place in the desired radial and longitudinal orientation. (Col. 6, line 27 to 32). "Next, the side branch guidewire 52 is withdrawn from the branch lumen 62 and the guide loop 14 and retracted to a position slightly behind the proximal end of the catheter balloon 56 as shown in FIG. 6." (Col. 6, lines 33 to 36). The side branch guidewire 52 is free to move back and forth longitudinally since the proximal end of the tissue supporting device has not been expanded. (Col. 6, lines 36 to 38).

Based on the foregoing it is clear that it is the tissue supporting device that is locked in place and not the side branch guidewire 52. A similar procedure for implanting a second tissue supporting device in the branch artery is described in the passage at Col. 7, lines 20 to 65 which is referred to by the Examiner. In that procedure the roles of the guidewires are reversed but the procedure is basically the same. Again, it is the tissue supporting device which is locked into place and not the main guidewire.

In fact, Shanley teaches away form using the tissue supporting device to pin the guidewire against the wall of the vessel. Specifically, Shanley states that "it is desirable to withdraw the side branch guidewire 52 while completing expansion of the tissue supporting device to avoid pinning the side branch guidewire between the expanded tissue supporting device 30 and the lumen wall." (Col. 6, lines 39 to 43). Clearly, a person of skill in the art would not use the device disclosed in Shanley in a manner which pins one of the guidewires between the tissue

supporting device and the wall of the vessel since a person of skill in the art would recognize that the guidewires must be withdrawn after deployment of the tissue supporting device. Therefore, contrary to the Examiner's assertion, the tissue supporting device disclosed in Shanley does not act as a stop.

Further, even if the tissue supporting device could be misused in a manner that would pin one of the guidewires between it and the wall of the vessel the limitation of these claims would still not be met. Specifically, the claims require that (1) the proximal portion of the third elongate tubular body is (2) "maintained within the lumen of the first elongate tubular body" by one or more magnetic or mechanical stops. First, it is clear that by the time the catheter has tracked over the main artery guidewire to the desired location at the junction of a body lumen the loop 14 is positioned at a distal portion of the branch artery guidewire 52. The proximal portion of the branch artery guidewire must extend out of the patient so the operator can manipulate the guidewire as necessary during the procedure. Second, as described above and as exemplified by FIG. 6 a proximal portion of guidewire 52 is not "maintained within the lumen" of loop 14. Guidewire 52 must be free to be withdrawn from loop 14 in order to be withdrawn proximally from the patient when the tissue support device is deployed. An operator would never leave any portion of the guidewire pinned between the tissue supporting device and the wall of the vessel. Clearly, Shanley does not teach or suggest a catheter in which the proximal portion of the third elongate tubular body is maintained within the lumen of the first elongate tubular body by one or more magnetic or mechanical stops as required by claims 1, 36, 42, 43, 45, and 72. Fogarty does not remedy this defect of Shanley. Therefore, claims 1, 36, 42, 43, 45, and 72 are allowable for at least these reasons. The remainder of the rejected claims depend from these claims and are allowable for at least these same reasons.

In view of the remarks above Applicant respectfully requests that the Examiner withdraw the rejections of the claims.

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Respectfully submitted,

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